



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/628,387	08/01/2000	Patrick Soon-Shiong	ABI1150-18	5713

30542 7590 08/22/2003

FOLEY & LARDNER
P.O. BOX 80278
SAN DIEGO, CA 92138-0278

EXAMINER

PULLIAM, AMY E

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 08/22/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/628,387

Applicant(s)

SOON-SHIONG ET AL.

Examiner

Amy E Pulliam

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 12-16, 58-60, 74-78, 128-131 and 145-147 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 12-16, 58-60, 74-78, 128-131 and 145-147 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 1615

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Request for Extension of Time and Request for Continued Examination, both received by the Office June 10, 2003.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 12-16, 58-60, 74-78, 128-131, and 145-147 provisionally rejected under the judicially created doctrine of double patenting over claims 179-181, 190-192, 205-208, 216-218, and 220 of copending Application No. 09/629,501. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: both applications are drawn to a unit dosage form comprising

Art Unit: 1615

cremophor free taxane in a sealed vial to be administered in a particular range over an administration period of not more than 3 hours.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 12-16, 58-60, 74-78, 128-131, and 145-147 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Elements which are critical or essential to the practice of the invention, but not included in the claim(s) are not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)), the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation; (b) the amount of guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the predictability of the prior art; (g) the breadth of the claims; and (h) the relative skill in the art.

(a) In order to utilize the system as claimed, the skilled artisan would be presented with an unpredictable amount of experimentation. An undetermined number of experimental factors

Art Unit: 1615

would be necessary to create a cremophor free unit dosage form comprising taxane. Without further clarification in the claim language, the skilled artisan would have an unpredictable amount of experimentation to create applicant's claimed invention, particular based on the state of this particular portion of the pharmaceutical art.

(b & c) The specification states, "in accordance with the present invention, there are provided compositions and methods useful for in vivo delivery of biologics, in the form of nanoparticles that are suitable for parenteral administration in aqueous suspension. [The] invention compositions comprise drugs, such as paclitaxel, stabilized by a polymer. The polymer is a biocompatible material, such as the protein albumin." This teaching clearly shows that Applicant's invention requires certain components, such as nanoparticles, in combination with a polymer, specifically the protein albumin. Applicant has defined their invention in this paragraph broadly, to include nanoparticles of the specific drug, stabilized by a polymer, and suspended in an aqueous solution for parenteral administration. However, not one of these particular, and obviously necessary elements, is present in the instant claims. There is no guidance presented in the specification to enable one skilled in the art to create the composition claimed without further components.

Additionally, at page 12, lines 12-13, Applicant states that it is very surprising that the invention formulation of paclitaxel, Capxol, a nanoparticles formulation, concentrates in tissues. Further, at lines 24-30 states that the basis for the unexpected results (localization within the prostate) could be a result of the specific particle size of the formulation (20-400 nm), or the presence of the protein albumin in the formulation. Again, it appears that the unexpected results of applicant's claimed invention are at least in part due to the formulation being nanoparticles,

Art Unit: 1615

and the formulation comprising albumin, however, neither of these limitations are recited in the broad claims. Based on the disclosures in the specification, applicant's invention appears to be a composition known as CapxolTM, which is a lyophilized powder, with a particular particle size range, containing paclitaxel and human serum albumin. Without further evidence, Applicant has provided no guidance for the vastly broad claims as instantly claimed. Particularly in light of Applicant's own statements that any unexpected results are due to the particle size and the particular polymer.

(d) The nature of systems for creating dosage forms comprising taxol, is extremely complex. As stated above, Applicant himself admits that the results of this invention as surprising, and are based on the inclusion of particular elements. It is necessary that these elements be included in the claim if they are essential to the showing of unexpected results.

(e & f) Although the art provides a certain level of guidance with regards to the creation of formulations comprising taxol, these teachings do not provide sufficient guidance where the specification is lacking. The art demonstrates that taxol formulations comprise cremophor. Applicant has created a formulation without cremophor. However, it appears from the specification that there are elements which are essential to the success of Applicant's invention which are not present in the claims. These essential elements must be included in the claim language, or they are not enabled by the disclosure.

(g) The claims are broad because there is no guidance for creating the formulation as claimed. It is necessary that Applicant include the essential elements to the invention.

(h) The level of skill of those in the art involving the creation of taxol formulations is high.

Art Unit: 1615

The skilled practitioner would first turn to the instant specification for guidance in making the claimed invention. However, the specification does not provide sufficient guidance. As such, the skilled practitioner would turn to the prior art for such guidance. However, the prior art does not offer the necessary guidance. Applicant has discovered a particular formulation, but has not claimed this particular formulation. Applicant is not enabled for the broad claims instantly claimed. It is recommended and advised that Applicant include the essential elements to the invention into the claims. As written, the creation of the claimed invention would require undue experimentation becomes the burden of the practitioner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
August 20, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600